The **Resolute Onyx** Short DAPT Program

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Cardiovascular Research Foundation

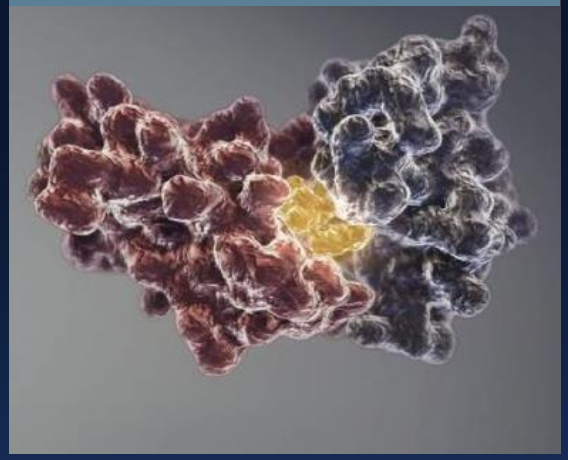
Disclosures

Global Chair for the Resolute Onyx Short DAPT Program - uncompensated

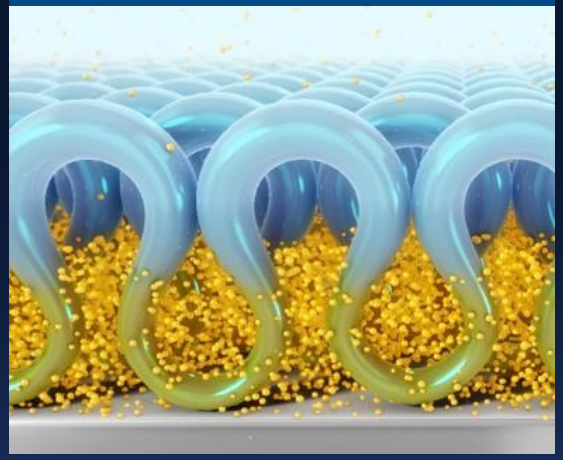
Resolute Onyx DES
Components

Potent sirolimus analogue

Zotarolimus Drug



BioLinx Polymer

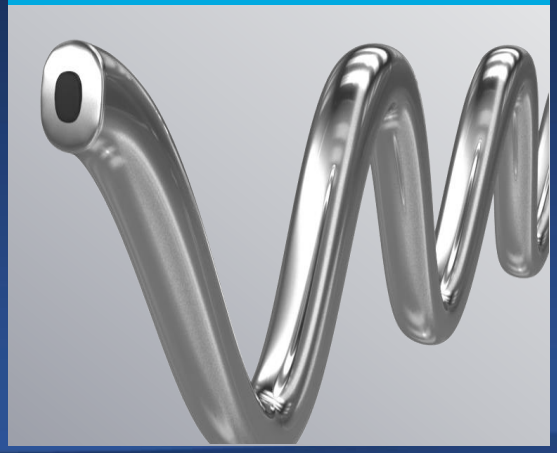


Hydrophilic
Biocompatible
Drug release in 180d

Flexible
Deliverable
Conformable

Continuous Sinusoid Technology

Core Wire Technology

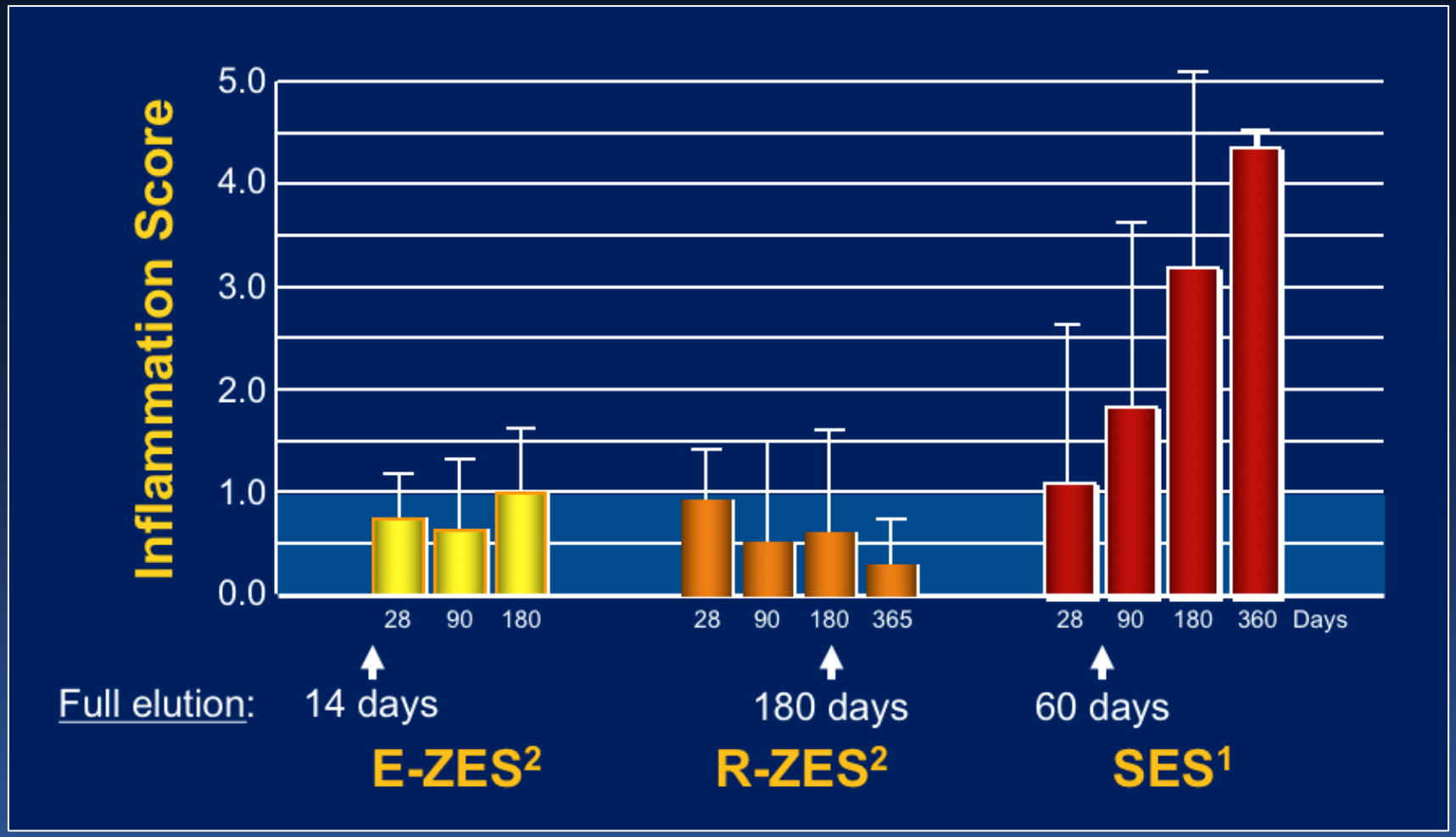


Cobalt alloy wire, platinum iridium core ⇒
Thin struts (81 µm)
Radio-opaque
Low recoil

Resolute Onyx
Short DAPT Rationale

- Preclinical studies suggest early healing
- Existing Resolute data suggesting early discontinuation is safe
  - Imaging data from ORION-OCT
  - Analysis of 4,896 RESOLUTE-treated pts
  - Results of BIONYX

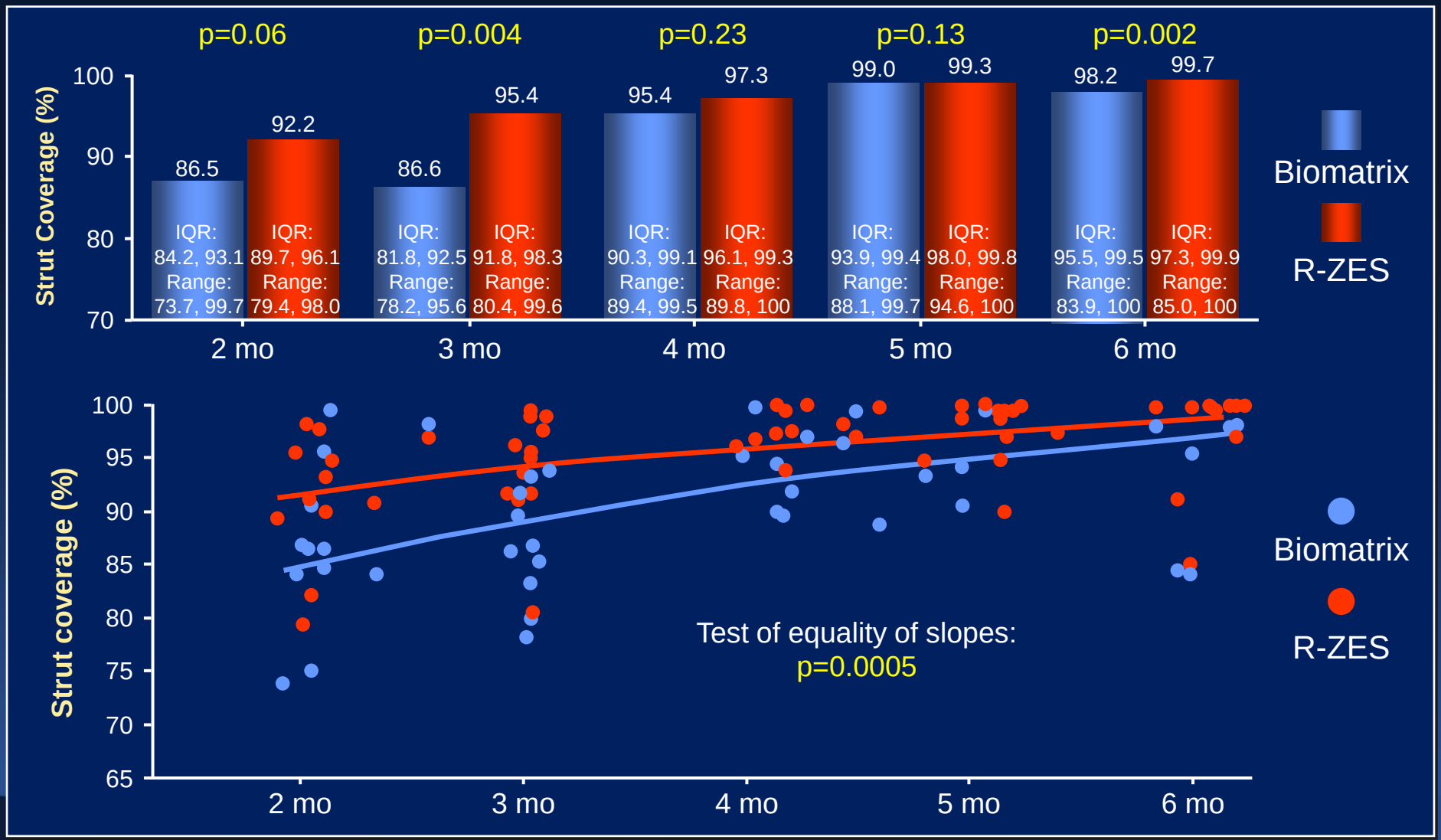
Inflammation Scores
Porcine Coronary Artery Implants



1. Data from Abbott Xience V US presentation SE2924433D
2. Data on file at Medtronic. Endeavor testing was not performed at 365 days

OCT-ORION Study

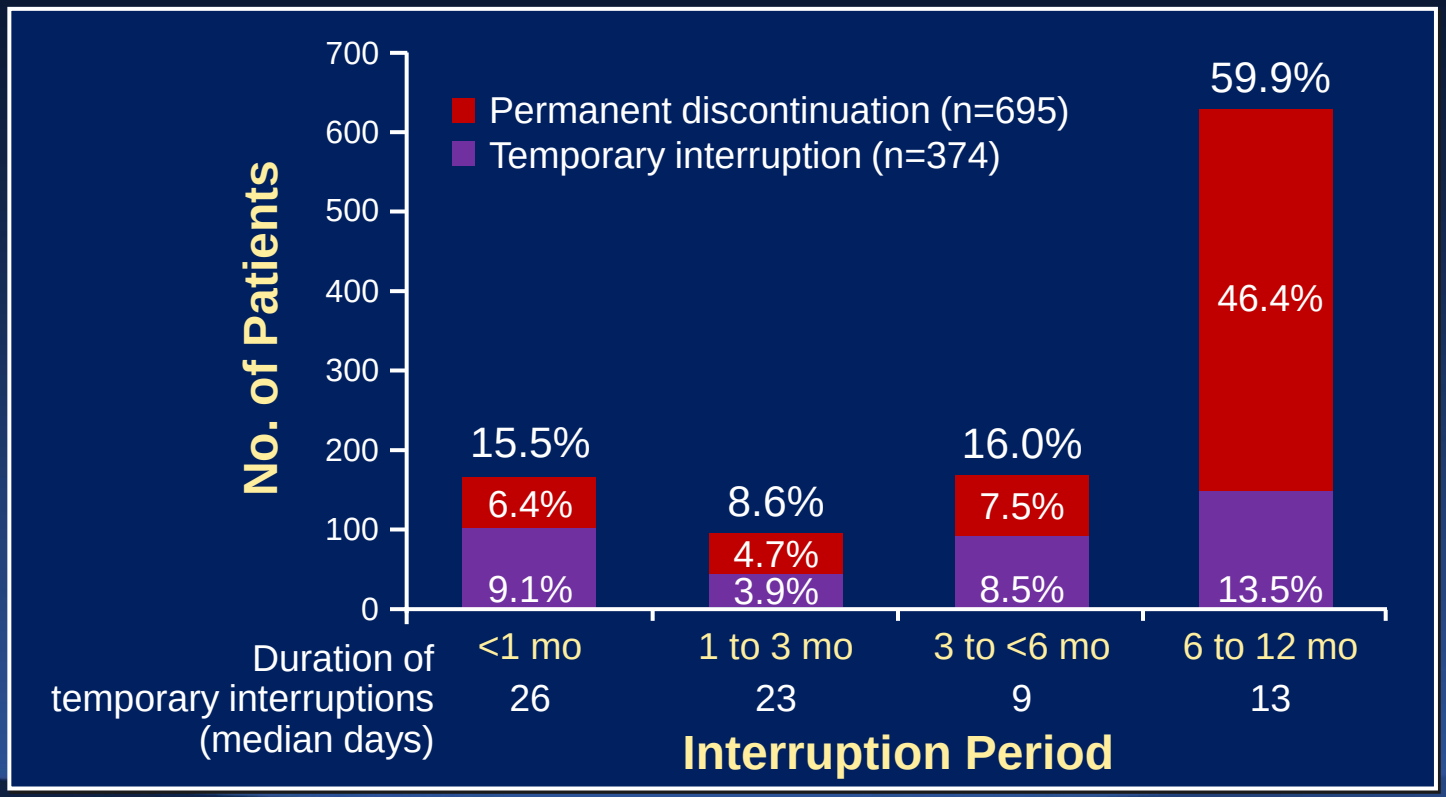
60 pts with MVD each treated with Resolute and Biomatrix DES in different vessels
OCT performed at 2 (n=12), 3 (n=12), 4 (n=11), 5 (n=12), 6 (n=13) and 12 (n=60) mos



Clinical evidence supporting 1 month DAPT for Resolute Onyx

Impact of DAPT Discontinuation After Resolute Zotarolimus-Eluting Stents

4,896 pts analyzed from the R-ZES global clinical studies program. Outcomes analyzed according to DAPT interruption from 0-1 month or >1-12 months.
Any interruption: 1,069 pts (21.8%) = 0-1 mo (n=166) + >1-12 mo (n=903)



Silber S et al. *EHJ* 2014;35:1949-56

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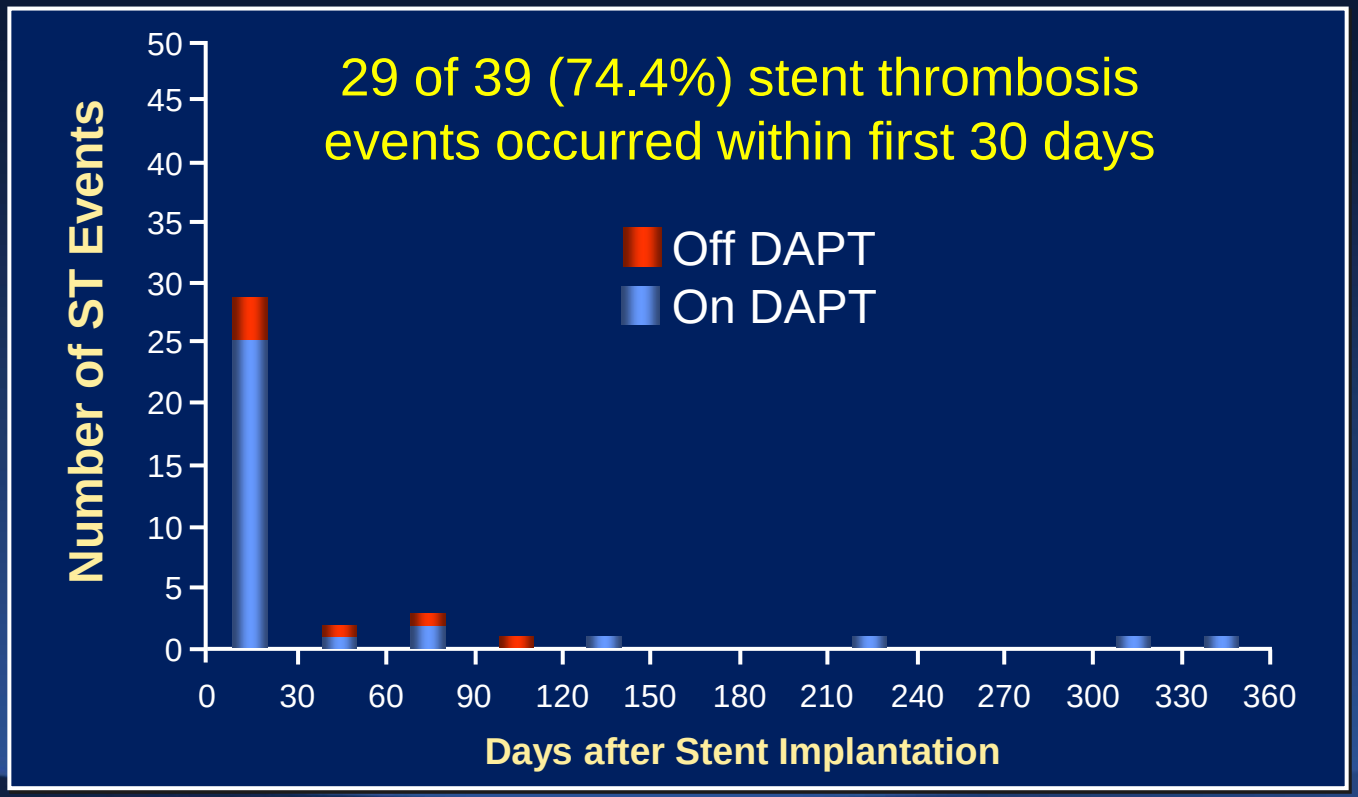
Timing of stent thrombosis, regardless of DAPT interruption



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Impact of DAPT Discontinuation After Resolute Zotarolimus-Eluting Stents

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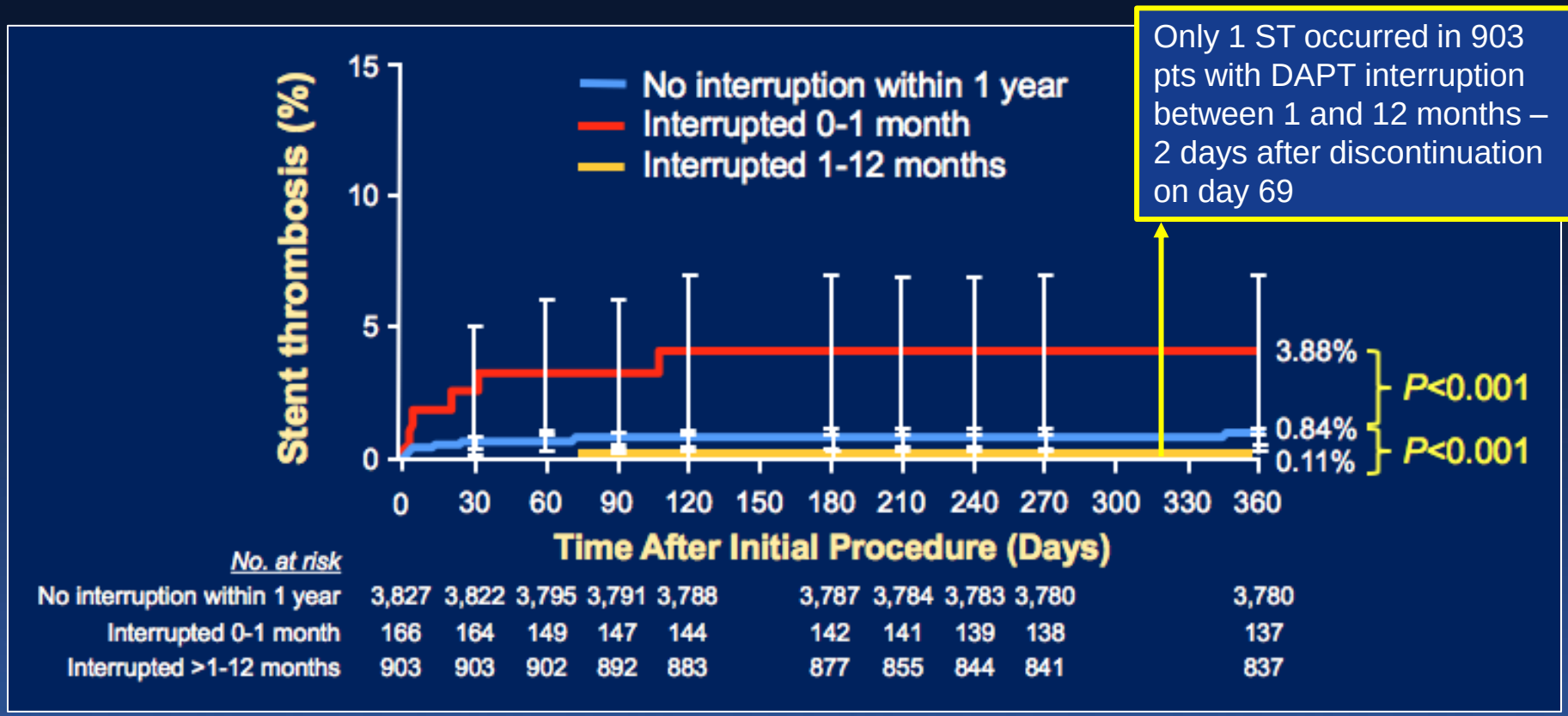
Relationship between DAPT interruption and ST



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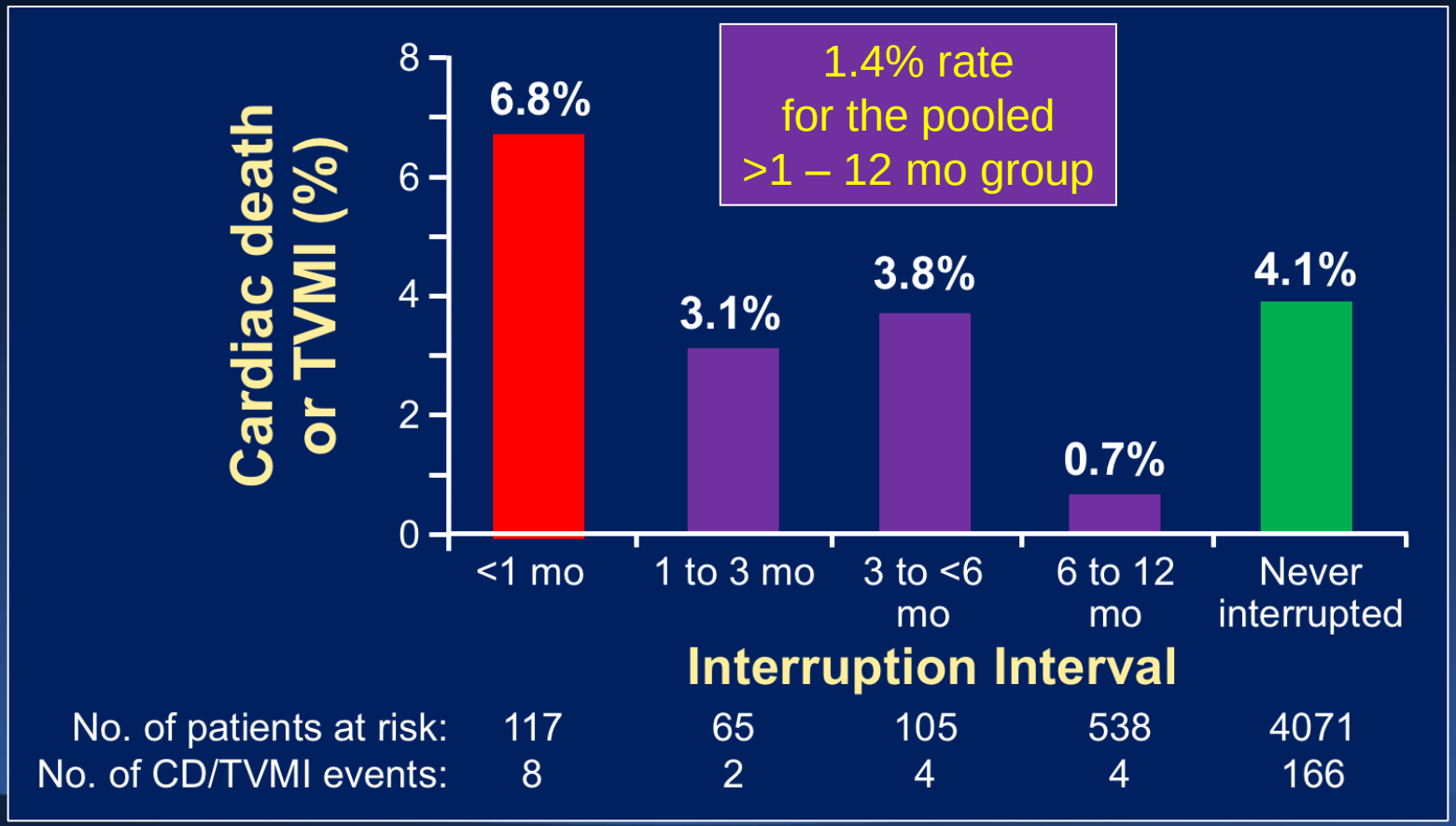
DAPT interruption for >14 days



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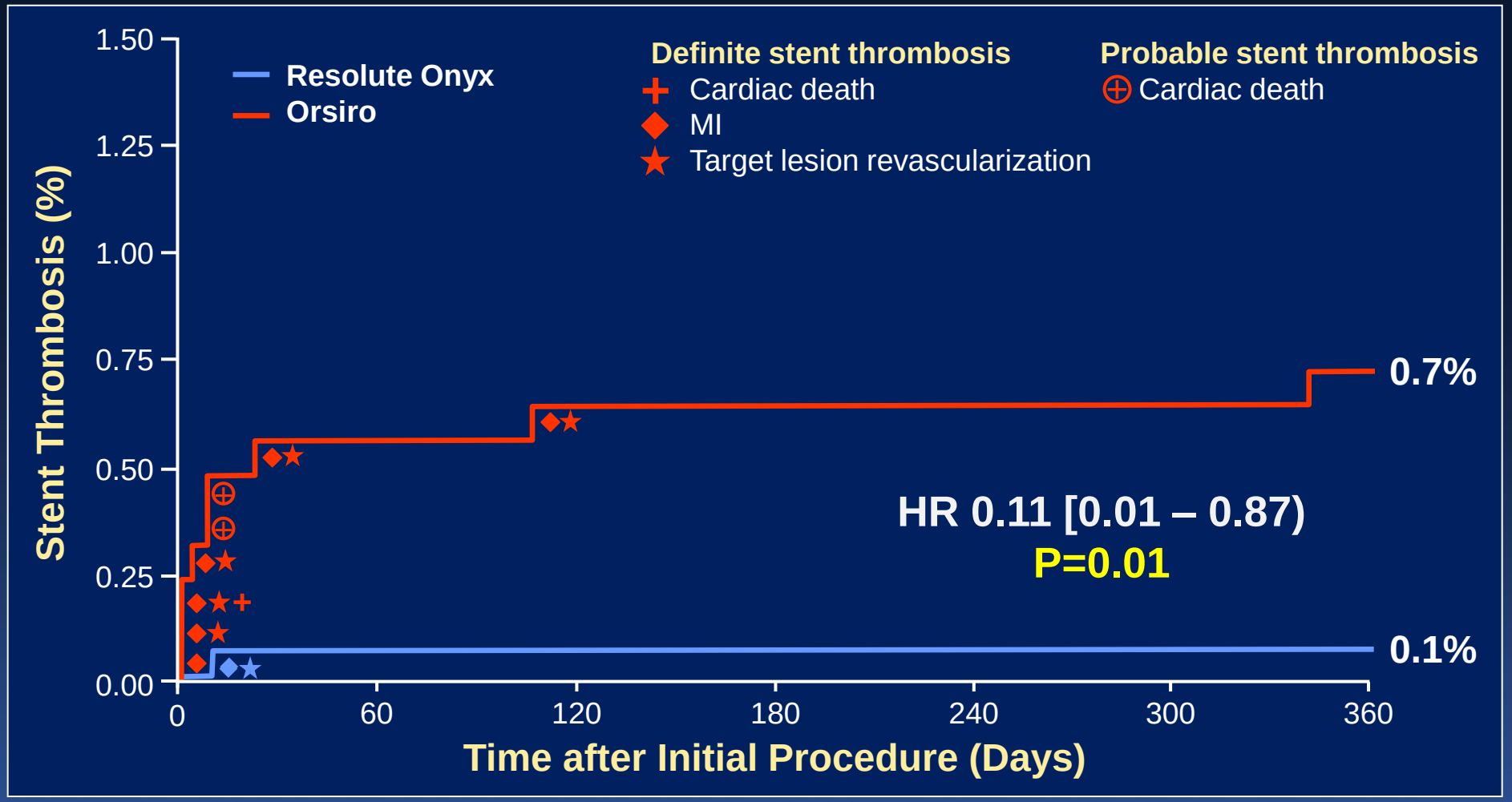
BIONYX: Onyx vs. Orsiro RCT (n=2,488)

Definite or probable stent thrombosis



Definite stent thrombosis: 0.1% vs. 0.6%, HR 0.14 [0.02 – 1.16], **P=0.03**

ONYX ONE Global RCT (n=2000)

Short-Term (1-Month) DAPT

Prospective, multicenter, single-blind randomized trial in high bleeding-risk patients undergoing PCI*

Resolute ONYX DES with 1-month DAPT (N=1000)	2000 patients* @ 85 global sites 1:1 randomization	BioFreedom DCS with 1-month DAPT (N=1000)

*Pts with ACS and stable angina undergoing PCI who are at increased risk of bleeding or in whom DAPT >1 month is undesirable (criteria similar to LEADERS FREE)

Antiplatelet Therapy: DAPT for 1 month, SAPT after 1 month

Primary endpoint: Composite of cardiac death, MI or stent thrombosis (def/prob) at 1 year

Major secondary endpoint (powered): Target lesion failure at 1 year

Other secondary endpoints: Acute procedural, device and lesion success; BARC bleeding; target vessel failure; all death, MI, stroke, revascularizations, TLF and MACE at all timepoints

Principal Investigator: Stephan Windecker

Co-principal Investigators: Elvin Kedhi and Azeem Latib

Study Chair: Gregg W. Stone

Sponsor: Medtronic

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ONYX ONE Global RCT (n=2000)

ONYX ONE CLEAR (n=1800)

Short-Term (1-Month) DAPT

Prospective, multicenter, single-arm study in high bleeding-risk patients undergoing PCI*

50 US and 5 Japanese sites

Resolute ONYX DES with 1-month DAPT (US & Japan N=800)**

+

Resolute ONYX DES with 1-month DAPT (from ONYX ONE N=1000)

85 global sites

*Pts with ACS and stable angina undergoing PCI who are at increased risk of bleeding or in whom DAPT >1 month is undesirable (criteria similar to LEADERS FREE)

**Up to an additional 100 patients may be enrolled from Japan

Antiplatelet Therapy: DAPT for 1 month, SAPT after 1 month

Primary endpoint: Composite of cardiac death or MI between 1 month and 1 year compared to a performance goal from HBR short DAPT studies

Secondary endpoints: Acute success; BARC bleeding, target vessel failure, revascularizations, all death, stroke, MACE, TLF

Co-Principal Investigators: David Kandzari and Ajay Kirtane

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ONYX ONE CLEAR (n=1800)

Short-Term (1-Month) DAPT

Enrollment complete!

Follow-up ongoing;

Results in 2020

Primary endpoint: Composite of cardiac death or MI between 1 month and 1 year compared to a performance goal from HBR short DAPT studies

Secondary endpoints: Acute success; BARC bleeding, target vessel failure, revascularizations, all death, stroke, MACE, TLF

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